FEB 14 2014

510(k) Summary for the NMI Dialysis Catheter

Date prepared: 11-Feb-2014

A. Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Lorraine M. Hanley
Vice President, Global Regulatory Affairs
508-494-1129

Or

Wanda M. Carpinella
Director, Global Regulatory Affairs
508-658-7929

C. Device Name

Trade Name:	NMI Dialysis Catheter (NMI DC)
Common/Usual name:	Catheter, Hemodialysis, Implanted
Classification Name:	Blood Access Device and Accessories 21CFR§876.5540, Class III
Classification Panel:	Gastroenterology/Urology

D. Predicate Device(s)

Common/Usual name:	Catheter, Hemodialysis, Implanted
Classification Name:	Blood Access Device and Accessories 21CFR§876.5540, Class III
Classification Panel:	Gastroenterology/Urology

Premarket Notification(s):
K121089, K101843

E. Device Description

The NMI Dialysis Catheter (NMI DC) is a Carbothane, double lumen catheter used to remove and return blood during hemodialysis and apheresis. The catheter lumens are 'D' shaped, open at the distal tip with a total of 4 side holes (two at venous tip, two at arterial tip). The distal venous tip extends beyond the arterial lumen to reduce recirculation. The distal tip is tapered and curved to facilitate insertion. The distal tip also includes a guidewire lumen to facilitate insertion by the optional guidewire placement technique.

The proximal section of the device contains a fixed polyester cuff that allows for tissue ingrowth for long term placement, an integrated bifurcation hub, suture wing, and extension leg set with color-coded occlusion clamps and luer connectors (red and blue for the arterial and venous lumens respectively). The lumen priming volumes are printed on the clamps. The procedure kit includes the necessary accessories to correctly insert the catheter.

The catheters are intended to be inserted percutaneously and are primarily placed in the right internal jugular vein of an adult patient. This implantation procedure is recommended to be carried out under direct fluoroscopic guidance.

The catheter shaft, bifurcation, and extension legs incorporate Endexo polymer for improved resistance to thrombus formation on the surfaces of the catheter.

F. Intended Use

The NMI Dialysis Catheter with ENDEXO Technology is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis. Catheters greater than 40 cm are intended for femoral vein insertion.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed device has similar materials, design and components and technological characteristics as predicate catheters. Both the NMI DC and predicate DuraMax Dialysis catheter are, in brief, intended for patients who require long-term vascular access for hemodialysis and apheresis. The only difference is the catheter, bifurcation and extension legs material. Both the proposed NMI DC and predicate DuraMax Dialysis catheter devices consist of a radiopaque polyurethane catheter shaft with barium sulfate for radiopacity; however the proposed NMI DC catheter shaft, bifurcation and extension legs also contain Endexo, a polymer technology which results in a material formulation that reduces the accumulation of thrombus. The predicate NMI PICC III catheter shaft also contains Endexo and a radiopaque polyurethane catheter shaft with barium sulfate for radiopacity.

H. Performance Data

The performance evaluation of the NMI DC included testing conducting in accordance with the following FDA guidance documents and international standards:

- EN ISO 10555-1:2009, Sterile, Single Use Intravascular Catheters – Part 1: General Requirements
- EN ISO 10555-3:1997, Sterile, Single Use Intravascular Catheters – Part 3: Central Venous Catheters
- FDA's "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheter dated March 16, 1995.
- Biocompatibility per ISO 10993-1

The proposed NMI DC successfully passed relevant testing per the above Guidance and standards including:

- Internal Product Specification Requirements
- Tensile Testing
- Recirculation Testing
- Mechanical Hemolysis
- Priming Volume
- Catheter Interface Compatibility
- In-Vitro and In-Vivo Thromboresistance Testing

I. Conclusion

Based on successful results of testing and on responses to questions posed in FDA's 510(k) Decision Making Tree, the proposed device is determined to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Navilyst Medical, Inc.
Lorraine M. Hanley
Vice President, Global Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K131260
Trade/Device Name: NMI Dialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: January 14, 2014
Received: January 15, 2014

Dear Lorraine M. Hanley,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if Known): ___K131260_____

Device Name: NMI Dialysis Catheter

Indications for Use:

The NMI Dialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis in adults.

Catheters greater than 40 cm are intended for femoral vein insertion.

Prescription Use (21 CFR 801 Subpart D)	☒	And/Or	AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C)	☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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